



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

MEMORANDUM

Date: January 8, 2007

To: BLA Committee

From: Lori A. Tull, RAC

Subject: STN 125197/0 Filing Action

I have reviewed the 3.2.A4 Novel Reagent (PA2024 fusion protein, an ancillary component of Sipuleucel-T) section(s) of Dendreon's BLA

(STN Number 125197/0) and find the application acceptable for filing.

(Signature of Committee Member)

(Supervisory Concurrence)